

K 961097

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DeRoyal Industries, Inc.
Electrosurgical Grounding Pad Adapters

510(k) Summary

SUMMARY OF THE SAFETY AND EFFECTIVENESS INFORMATION
UPON WHICH
AN EQUIVALENCE DETERMINATION COULD BE BASED

SUBMITTER INFORMATION

NAME: DeRoyal Industries, Inc.
ADDRESS: 200 DeBusk Lane
Powell, TN 37849

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CONTACT: Debra F. Manning
DATE OF PREPARATION: March 18, 1996

DEVICE NAMES

NAME: DeRoyal Surgical (SurgiMate) Electrosurgical Grounding Pad Adapters
COMMON/USUAL NAME: Electrosurgical Grounding Pad Adapters
CLASSIFICATION NAME (if known): Electrosurgical Cutting & Coagulation Device & Accessories

PREDICATE OR LEGALLY MARKETING DEVICES

3M
Birtcher
ValleyLab

DEVICE DESCRIPTION

The DeRoyal Surgical Electrosurgical Grounding Pad Adapter functions in the same manner as predicate devices in that it is used to connect one type of electrosurgical grounding pad to a particular type of jack on the electrosurgical cautery machine being used.

Device Design/Materials Used/Physical Properties: The DeRoyal Grounding Pad Adapter is made of materials commonly used for their purpose. The concept of use is that the adapter converts one type of connection to another type of connection without any alteration of the circuit or any impact on the performance of the original circuit.

DEVICE INTENDED USE

The DeRoyal Grounding Pad Adapter is indicated for use whenever the ESU machine requires a grounding pad of the type provided by SurgiMate, or the connector on the SurgiMate pad does not match the intended jack of the ESU machine but its use would make the electrical connection compatible.

TECHNOLOGICAL COMPARISON WITH PREDICATE OR LEGALLY MARKETING DEVICE(S)

Characteristic	DeRoyal Device	Other Devices
Input Connector	Proprietary grounding pad connector	Same
Output Connector	Target machine connector	Same
Sterility	Non-sterile	Same
Circuit	Direct wiring from input connector to output connector	Same